ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Pack of 20 or 72 syringes and cleaning towels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seclaris DC 250 mg intramammary suspension for dry cows

Cefalonium (as dihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each intramammary syringe of 3 g contains 250 mg of cefalonium (as dihydrate).

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

20 syringes + cleaning towels
72 syringes + cleaning towels

5. TARGET SPECIES

Cattle (dry cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat & offal: 21 days
Milk: 96 hours after calving if the dry period is longer than 54 days
58 days following the treatment if the dry period is less than or equal to 54 days

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cefalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

EXP:
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4139

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe of 3 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seclaris DC 250 mg intramammary suspension for dry cows
Cefalonium (as dihydrate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalonium (as cefalonium dihydrate): 250 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal: 21 days
Milk: 96 hours after calving if dry period > 54 days
58 days following the treatment if dry period ≤ 54 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Seclaris DC 250 mg intramammary suspension for dry cows

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Lohmann Pharma Herstellung GmbH
Heinz-Lohmann-Strasse 5
Cuxhaven – Niedersachsen- 27472
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seclaris DC 250 mg intramammary suspension for dry cows

Cefalonium (as dihydrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each intramammary syringe of 3 g contains 250 mg of cefalonium (as dihydrate).
Shiny off-white to yellowish ointment.

4. INDICATION(S)

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp susceptible to cefalonium.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cefalosporins, other ß-lactam antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases immediate hypersensitivity reactions were observed in some animals (restlessness, tremors, swelling of mammary gland, eyelids and lips). These reactions may lead to death.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (dry cows).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramammary use.
The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation.

9. ADVICE ON CORRECT ADMINISTRATION

After milking is complete, thoroughly clean and disinfect the end of the teat with the cleaning towel provided. There are two options for administration of the product:
Option 1: Short nozzle intramammary administration: Hold the barrel of the syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the syringe) Take care not to contaminate the nozzle.
Option 2: Full nozzle intramammary administration: Remove the cap fully by holding the barrel of the syringe firmly in one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.
Insert the nozzle into the teat canal and apply steady pressure on the syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.
After infusion, it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

10. WITHDRAWAL PERIOD(S)

Meat & offal: 21 days
Milk: 96 hours after calving if the dry period is longer than 54 days
58 days following the treatment if the dry period is less than or equal to 54 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and syringe after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
None

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of bacteria isolated from milk samples obtained from the udder quarter(s) of each cow to be dried off. If this is not possible, therapy should be based on local (regional, farm level) risk based epidemiological information about the expected pathogen challenge, and susceptibility of target bacteria. Use of the product deviating from the instructions given in the SPC may contribute to the development of bacterial resistance to cefalonium which may also decrease the effectiveness of treatment with other beta lactams. Dry cow therapy protocols should take local and national policies on antimicrobial use into consideration, and undergo regular veterinary review.
The feeding to calves of milk containing residues of cefalonium that could select for antimicrobial-resistant bacteria (e.g. ESBL) should be avoided up to the end of the milk withdrawal period, except during the colostral phase.

The efficacy of the product is only established against the pathogens mentioned in Section “Indications”. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly *Pseudomonas aeruginosa*, can occur after drying off. Good hygienic practices should be thoroughly respected in order to reduce this risk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
Penicillin and cefalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cefalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the Doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention. The cleaning towels supplied with this product contain isopropyl alcohol, which may cause skin or eye irritation in some people. It is recommended to wear protective gloves when administering the product and handling the cleaning towels.

Interaction with other medicinal products and other forms of interaction:
Cefalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cefalosporins and nephrotoxic drugs may increase renal toxicity.

Pregnancy and lactation:
Intended for use during the last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus.
Do not use in cows that are lactating.

Overdose (symptoms, emergency procedures, antidotes):
Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

Incompatibilities
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

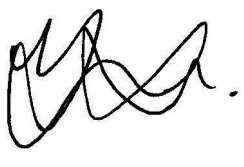
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Single dose 3g white polyethylene syringes with red cap.
Cleaning towels (70% viscose / 30% polyester, alcohol impregnated) in paper aluminium copolymer laminate sachet.

Pack size:
20 intramammary syringes and 20 cleaning towels
72 intramammary syringes and 72 cleaning towels
Not all pack sizes may be marketed.



Approved: 06 October 2022